

New Docket No.: 23558-028

Application No. 10/712,266

Page 2 of 19

In the claims:

Please cancel claims 1-70 and add the following claims:

71. (New) A method of determining the status of a subject, the method including:

a) Obtaining subject data from cells in a biological sample obtained from the subject, the subject data being obtained from a single test and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject;

b) Comparing the subject data to predetermined data, the predetermined data including for each of a plurality of conditions:

i) Values for at least some of the parameters; and,

ii) An indication of the condition; and,

c) Determining the status of the subject in accordance with the results of the comparison, the status indicating at least one of the presence, absence or degree of one or more of the conditions.

72. (New) A method according to claim 71, the indication of the condition including at least one of:

a) An indication of the stage of a condition;

b) An indication of the degree of a condition; and

c) An indication of the degree of health of a subject.

73. (New) A method according to claim 71, the number of parameters being sufficiently statistically significant to allow a number of conditions to be distinguished.

74. (New) A method according to claim 71, the number of parameters being greater than 100.

75. (New) A method according to claim 71, the number of parameters being greater than 1000.

76. (New) A method according to claim 71, the number of parameters being less than 6000.

77. (New) A method according to claim 71, the method including generating a report representing the status of the subject.

New Docket No.: 23558-028

Application No. 10/712,266

Page 3 of 19

78. (New) A method according to claim 71, the method including determining the ability of the subject to perform in a sporting and/or racing event in accordance with at least one of the presence, absence or degree of any conditions.

79. (New) A method according to claim 71a, the parameters being representative of the level or abundance of a molecule selected from one or more of :

- a) A nucleic acid molecule;
- b) A proteinaceous molecule;
- c) An amino acid
- d) A carbohydrate;
- e) A lipid;
- f) A steroid;
- g) An inorganic molecule;
- h) An ion;
- i) A drug;
- j) A chemical;
- k) A metabolite;
- l) A toxin;
- m) A nutrient;
- n) A gas;
- o) A cell;
- p) A pathogenic organism; and,
- q) A non pathogenic organism.

80. (New) A method according claim 71, the parameters being determined from:

- a) Blood samples; and,
- b) Samples containing cells of the immune system.

81. (New) A method according to claim 71, the predetermined data including phenotypic information of the individuals, and the subject data including phenotypic information regarding the subject, the phenotypic information including details of one or more phenotypic traits.

82. (New) A method according to claim 81, the method including comparing the subject data to predetermined data for individuals having one or more phenotypic traits in common with the subject.

New Docket No.: 23558-028

Application No. 10/712,266

Page 4 of 19

83. (New) A method according to claim 71, the predetermined data being diagnostic signatures, the method including determining a diagnostic signature for a respective condition by data mining subject data relating to a number of individuals having known conditions, or degrees of conditions, each diagnostic signature including a range of values for at least some of the parameters.

84. (New) A method according to claim 83, the subject data being determined by at least one of:

- a) Clinical trials; and,
- b) Diagnosis of conditions within subjects.

85. (New) A method according to claim 84, the diagnosis being performed in accordance with the method comprising the steps of:

a) Obtaining subject data from cells in a biological sample obtained from the subject, the subject data being obtained from a single test and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject;

b) Comparing the subject data to predetermined data, the predetermined data including for each of a plurality of conditions:

- i) Values for at least some of the parameters; and,
- ii) An indication of the condition;

c) Determining the status of the subject in accordance with the results of the comparison, the status indicating at least one of the presence, absence or degree of one or more of the conditions; and,

being subsequently confirmed by a medical practitioner or veterinarian.

86. (New) A method according to claim 71, the predetermined data being diagnostic signatures, the method including determining a diagnostic signature for a respective condition by:

- a) Obtaining data relating to a number of individuals, the data including:
 - i) An indication of the status of the individual;
 - ii) Respective values for each of the plurality of parameters;

RECEIVED
CENTRAL FAX CENTER
MAY 14 2008

New Docket No.: 23558-028
Application No. 10/712,266
Page 5 of 19

b) Selecting one or more groups of individuals in accordance with the status of the individuals and the condition; and,

c) Determining a range of parameter values for each group in accordance with the parameter values of the individuals, the range of parameter values representing a diagnostic signature for the respective group.

87. (New) A method according to claim 86, the method including:

a) Comparing the data for each of the individuals to predetermined criteria; and,
b) Selectively excluding one or more individuals from a respective group in accordance with the results of the comparison.

88. (New) A method according to claim 87, the method including:

a) Receiving confirmation of the determined status;
b) Comparing the data for each of the individuals to predetermined criteria; and,
c) Updating the predetermined data in accordance with the confirmed status and the subject data in response to a successful comparison.

89. (New) A method according to claim 87, the predetermined criteria representing quality control criteria.

90. (New) A method according to claim 87, the method including:

a) Comparing the data for each of the individuals to each other; and,
b) Selectively excluding one or more individuals from a respective group in accordance with the results of the comparison.

91. (New) A method according to claim 87, the method including, for each selected group:

a) Determining parameters that allow the group to be distinguished from each other group; and,

b) Determining a range of parameter values for the selected parameters in accordance with the parameter values of the individuals in the group.

92. (New) A method according to claim 87, the method including for each condition:

a) Determining parameters that allow the degree of the condition to be determined; and,
b) Determining a range of parameter values for the selected parameters taking account of the relationship between these parameter values and the degree of the condition.

New Docket No.: 23558-028

Application No. 10/712,266

Page 6 of 19

93. (New) A method according to claim 87, the method including for each diagnostic signatures:

- a) Obtaining data for an individual having the respective condition;
- b) Comparing the parameter values for the individual to the respective diagnostic signature; and,
- c) Revising the diagnostic signature in accordance with an unsuccessful comparison.

94. (New) A method according to claim 71, the method being performed using a system including at least one end station coupled to a base station *via* a communications network, the method including causing the base station to:

- a) Receive the subject data from the end station *via* the communications network;
- b) Determine the status of the subject;
- c) Transfer an indication of the subject status to the end station *via* the communications network.

95. (New) A method according to claim 71, the subjects and individuals being at least one of:

- a) Horses;
- b) Camels;
- c) Greyhounds;
- d) Human Athletes; and,
- e) Other Performance animals.

96. (New) Apparatus for determining the status of a subject, the apparatus including a processing system adapted to:

- a) Obtain subject data from cells in a biological sample obtained from the subject, the subject data being obtained from a single test and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject; b) Compare the subject data to predetermined data, the predetermined data including for each of a plurality of conditions:
 - i) A range of values for at least some of the parameters; and,
 - ii) An indication of the condition; and,

New Docket No.: 23558-028

Application No. 10/712,266

Page 7 of 19

c) Determine the status of the subject in accordance with the results of the comparison, the status indicating at least one of the presence, absence or degree of one or more of the conditions.

97. (New) Apparatus according to claim 96, the apparatus being adapted to perform the method comprising the steps of

a) Obtaining subject data from cells in a biological sample obtained from the subject, the subject data being obtained from a single test and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject;

b) Comparing the subject data to predetermined data, the predetermined data including for each of a plurality of conditions:

i) Values for at least some of the parameters; and,

ii) An indication of the condition; and,

c) Determining the status of the subject in accordance with the results of the comparison, the status indicating at least one of the presence, absence or degree of one or more of the conditions.

98. (New) A computer program product for determining the status of a subject, the computer program product including computer executable code which when executed on a suitable processing system causes the processing system to perform the method of claim 71.

99. (New) A method of determining diagnostic signatures for use in the status determination of a subject, the method including:

a) Obtaining data from cells in a biological sample obtained from each of a number of individuals, the data being obtained from a single test for each individual and including:

i) An indication of the status of the individual, including an indication of at least one definitively diagnosed condition;

ii) Respective values for each of a plurality of parameters, the individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells;

b) Selecting one or more groups of individuals in accordance with the status of the individuals and the condition; and,

New Docket No.: 23558-028
Application No. 10/712,266
Page 8 of 19

c) Determining a range of parameter values for each group in accordance with the parameter values of the individuals, the range of parameter values representing a diagnostic signature for the respective group.

100. (New) A method according to claim 99, the method including, for each selected group:

a) Determining parameters that allow the group to be distinguished from each other group; and,

b) Determining a range of parameter values for the selected parameters in accordance with the parameter values of the individuals in the group.

101. (New) A method according to claim 99, the method including for each diagnostic signatures:

a) Obtaining data for an individual having the respective condition;

b) Comparing the parameter values for the individual to the respective diagnostic signature; and,

c) Revising the diagnostic signature in accordance with an unsuccessful comparison.

102. (New) A method according to claim 99, the data for each of the individuals being determined by at least one of:

a) Clinical trials; and,

b) Diagnosis of conditions within subjects.

103. (New) A method according to claim 102, the diagnosis of conditions being performed by:

a) Determining the status of the individual in accordance with the method of claim 1; and,

b) Having the status subsequently confirmed by a medical practitioner or veterinarian.

104. (New) A method according to claim 103, the method including:

a) Receiving confirmation of the determined status;

b) Comparing the data for each of the individuals to predetermined criteria; and,

c) Updating the predetermined data in accordance with the confirmed status and the subject data in response to a successful comparison.

105. (New) A method according to claim 99, the method including:

a) Comparing the data for each of the individuals to predetermined criteria; and,

New Docket No.: 23558-028

Application No. 10/712,266

Page 9 of 19

b) Selectively excluding one or more individuals from a respective group in accordance with the results of the comparison.

106. (New) A method according to claim 104, the predetermined criteria representing quality control criteria.

107. (New) A method according to claim 104, the method including:

- a) Comparing the data for each of the individuals to each other; and,
- b) Selectively excluding one or more individuals from a respective group in accordance with the results of the comparison.

108. (New) A method according to claim 109, the conditions including at least one of:

- a) A disease; and,
- b) An assessment that the individual is healthy.

109. (New) A method of allowing a user to determine the status of a subject using a base station, the method including causing the base station to:

a) Receive subject data from the user *via* a communications network, the subject data being obtained from cells in a biological sample obtained from the subject and being obtained from a single test and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject;

b) Compare the subject data to predetermined data, the predetermined data including for each of a plurality of conditions:

- i) Values for at least some of the parameters; and,
- ii) An indication of the condition; and,

c) Determine the status of the subject in accordance with the results of the comparison, the status indicating the presence and/or absence of the one or more conditions; and,

d) Transfer an indication of the status of the subject to the user *via* the communications network.

110. (New) A method according to claim 109, the method including:

- a) Having the user determine the subject data using a remote end station; and,
- b) Transferring the subject data from the end station to the base station *via* the communications network.

New Docket No.: 23558-028

Application No. 10/712,266

Page 10 of 19

111. (New) A method according to claim 110, the base station including first and second processing systems, the method including:

- a) Transferring the subject data to the first processing system;
- b) Transferring the subject data to the second processing system; and,
- c) Causing the second processing system to perform the comparison.

112. (New) A method according to claim 111, the method including:

- a) Transferring the results of the comparison to the first processing system; and,
- b) Causing the first processing system to determine the status of the subject.

113. (New) A method according to claim 111, the method including at least one of:

- a) Transferring the subject data between the communications network and the first processing system through a first firewall; and,
- b) Transferring the subject data between the first and the second processing systems through a second firewall.

114. (New) A method according to claim 111, the second processing system being coupled to a database adapted to store the predetermined data, the method including:

- a) Querying the database to obtain at least selected predetermined data from the database; and,
- b) Comparing the selected predetermined data to the subject data.

115. (New) A method according to claim 111, the second processing system being coupled to a subject database, the method including storing the subject data in the subject database.

116. (New) A method according to claim 109, the method including having the user determine the subject data using a secure array, the secure array of elements capable of determining the quantity of a biological molecule and having a number of features each located at respective position(s) on the array, and a respective code, the method including causing the base station to:

- a) Determine the code from the subject data;
- b) Determine a layout indicating the position of each feature on the array;
- c) Determine the parameter values in accordance with the determined layout, and the subject data.

New Docket No.: 23558-028

Application No. 10/712,288

Page 11 of 19

117. (New) A method according to claim 107, the method including having the user determine the subject data using a secure array of elements capable of determining the quantity of a biological molecule, the secure array having a number of features each tagged with an identifier determining the type of biological molecule to which they bind, and a respective code, the method including causing the base station to:

- a) Determine the code from the subject data;
- b) Determine a layout indicating the position of each feature on the array;
- c) Determine the parameter values in accordance with the determined layout, and the subject data.

118. (New) A method according to claim 109, the method including causing the base station to:

- a) Determine payment information, the payment information representing the provision of payment by the user; and,
- b) Perform the comparison in response to the determination of the payment information.

119. (New) A method according to claim 109, the method being performed in accordance with the steps of

a) Obtaining subject data from cells in a biological sample obtained from the subject, the subject data being obtained from a single test and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject;

b) Comparing the subject data to predetermined data, the predetermined data including for each of a plurality of conditions:

- i) Values for at least some of the parameters; and,
- ii) An indication of the condition; and,

c) Determining the status of the subject in accordance with the results of the comparison, the status indicating at least one of the presence, absence or degree of one or more of the conditions..

120. (New) A base station for determining the status of a subject, the base station including:

New Docket No.: 23558-028

Application No. 10/712,266

Page 12 of 19

a) A store method for storing predetermined data, the predetermined data including for each of a plurality of conditions:

i) Values for at least some of the parameters; and,

ii) An indication of the condition; and,

b) A processing system, the processing system being adapted to:

i) Receive subject data from the user *via* a communications network, the subject data being obtained from cells in a biological sample obtained from the subject, being obtained from a single test, and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject;

ii) Compare the subject data to the predetermined data;

iii) Determine the status of the subject in accordance with the results of the comparison; and,

iv) Output an indication of the status of the subject to the user *via* the communications network.

121. (New) A base station according to claim 120, the processing system being adapted to receive subject data from a remote end station adapted to determine the subject data.

122. (New) A base station according to claim 120, the processing system including:

a) A first processing system adapted to:

i) Receive the subject data; and

ii) Determine the status of the subject in accordance with the results of the comparison; and,

b) A second processing system adapted to:

i) Receive the subject data from the processing system; and,

ii) Perform the comparison; and,

iii) Transfer the results to the first processing system.

123. (New) A base station according to claim 122, the base station including:

a) A first firewall for coupling the first processing system to the communications network; and,

b) A second firewall for coupling the first and the second processing systems.

RECEIVED
CENTRAL FAX CENTER**MAY 14 2008**New Docket No.: 23558-028
Application No. 10/712,266
Page 13 of 19

124. (New) A base station according to claim 122, the processing system being coupled a subject database, the processing system adapted to store the subject data in the subject database.

125. (New) A base station according to claim 122, the method of performing the comparison including causing the second processing system to:

- a) Obtain the predetermined data in the form of a set of signatures; and,
- b) Use the signatures to classify the subject data into a respective one of the groups.

126. (New) A base station according to claim 120, the subject data being determined using a secure array, the secure array having a number of features each located at respective position on the array, and a respective code, the processing system being adapted to:

- a) Determine the code from the subject data;
- b) Determine a layout indicating the position of each feature on the array;
- c) Determine the parameter values in accordance with the determined layout, and the subject data.

127. (New) A base station according to claim 120, the method including having the user determine the subject data using a secure array of elements capable of determining the quantity of a biological molecule, the secure array having a number of features each tagged with an identifier determining the type of biological molecule to which they bind, and a respective code, the method including causing the base station to:

- a) Determine the code from the subject data;
- b) Determine a layout indicating the position of each feature on the array;
- c) Determine the parameter values in accordance with the determined layout, and the subject data.

128. (New) A base station according to claim 120, the base station being adapted to perform the method of

- a) Receiving subject data from the user *via* a communications network, the subject data being obtained from cells in a biological sample obtained from the subject and being obtained from a single test and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject;

New Docket No.: 23558-028
Application No. 10/712,266
Page 14 of 19

- b) Comparing the subject data to predetermined data, the predetermined data including for each of a plurality of conditions:
 - i) Values for at least some of the parameters; and,
 - ii) An indication of the condition; and,
- c) Determining the status of the subject in accordance with the results of the comparison, the status indicating the presence and/or absence of the one or more conditions; and,
- d) Transferring an indication of the status of the subject to the user *via* the communications network.

129. (New) An end station adapted to determine the status of a subject, the end station including a processor adapted to:

a) Determine subject data from cells in a biological sample obtained from the subject, the subject data being obtained from a single test and including the subject data including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene expression product in the cells, the parameter values being indicative of the current biological status of the subject;

b) Transfer the subject data to a base station *via* a communications network, the base station being adapted to:

i) Compare the subject data to predetermined data for one or more individuals, the predetermined data including:

- (1) (New) One or more parameter values for the respective individual; and,
- (2) An indication of the status of each individual; and,

ii) Determine the status of the subject in accordance with the results of the comparison; and,

c) Receive an indication of the status of the subject *via* the communications network.

130. (New) An end station according to claim 129, the end station being used in the method comprising the steps of

a) Receiving subject data from the user *via* a communications network, the subject data being obtained from cells in a biological sample obtained from the subject and being obtained from a single test and including respective values for each of a plurality of parameters, individual parameters being representative of the level, abundance or functional activity of a gene

RECEIVED
CENTRAL FAX CENTER

New Docket No.: 23558-028
Application No. 10/712,266
Page 15 of 19

MAY 14 2008

expression product in the cells, the parameter values being indicative of the current biological status of the subject;

b) Comparing the subject data to predetermined data, the predetermined data including for each of a plurality of conditions:

i) Values for at least some of the parameters; and,

ii) An indication of the condition; and,

c) Determining the status of the subject in accordance with the results of the comparison, the status indicating the presence and/or absence of the one or more conditions; and,

d) Transferring an indication of the status of the subject to the user *via* the communications network.

131. (New) A method of providing secure arrays for use, each array including a number of predetermined features, the method including:

a) Determining a number of respective feature layouts, each layout representing the positioning of each feature on a respective array;

b) Determining a number of codes, each code corresponding to a respective layout;

c) Generating a number of arrays, each array being generated in accordance with:

i) a respective layout, and including the corresponding code thereon, the code being used in processing the array; and,

ii) as a self assembled random array of tagged features, each feature coded with information describing the molecular identity of the probe which it contains, and including the corresponding code thereon, the code being used in processing the array. a respective layout, and including the corresponding code thereon, the code being used in processing the array.

132. (New) A method according to claim 131, the method being performed to provide the arrays on behalf of an entity, the method including providing an indication of the layouts and corresponding codes to the entity, to thereby allow the entity to process the arrays.

133. (New) A method according to claim 131, the method of determining the layouts including:

a) Determining a preferred layout; and,

b) Moving the position of one or more of the features from the position in the preferred layout to alternative position.

134. (New) A method according to claim 133, the method including:

New Docket No.: 23558-028

Application No. 10/712,266

Page 16 of 19

- a) Determining the type of each feature; and,
- b) Exchanging the position of one or more features having different feature types.

135. (New) A method comprising:

- a) for each of a plurality of conditions:
 - i) for each of a plurality of animals having a known status, measuring a plurality of biological factors potentially indicative of said status;
 - ii) analysing said biological factors to obtain at least one model providing a statistical correlation between said biological factors and said status;
 - iii) storing at least one said model; and
- b) responsive to a request for status determination of a particular animal, the request including, for the particular animal, measures of at least some of the number of biological factors potentially indicative of said status, the factors being obtained from cells in a biological sample, the sample being obtained from the particular animal in a single test, the factors being representative of the level, abundance or functional activity of a gene expression product in the cells, applying at least one stored model to the information in the request in order to attempt to determine the status of the particular animal.

136. (New) A method comprising:

- a) for each of a plurality of conditions:
 - i) for each of a plurality of animals having the condition, measuring a plurality of biological factors potentially indicative of said condition;
 - ii) determining at least one model that provides a statistical correlation between said biological factors and said condition;
 - iii) storing at least one said model; and

b) responsive to a request for status determination of a particular animal, the request including, for the particular animal, measures of the plurality of biological factors potentially indicative of said status, the factors being obtained from cells in a biological sample, the sample being obtained from the particular animal in a single test, the factors being representative of the level, abundance or functional activity of a gene expression product in the cells, applying stored model to the information in the request in order to attempt to determine the status of the particular animal.

137. (New) A method comprising:

New Docket No.: 23558-028

Application No. 10/712,266

Page 17 of 19

a) providing a system including a database of (a) a plurality of statistical models that correlate biological factors to known conditions, and (b) statistical models that correlate known conditions or biological factors to known statuses;

b) responsive to a user request for a status determination for a particular animal, said request including measures of a plurality biological factors, the factors being obtained from cells in a biological sample, the sample being obtained from the particular animal in a single test, the factors being representative of the level, abundance or functional activity of a gene expression product in the cells, applying a plurality statistical model from the database to at least some of the biological factors in the request in order to determine whether the animal has a known condition or a known status; and

c) providing the user with the status determination.

138. (New) A method as in claim 137 wherein the user is at a remote location from the database and wherein the user is only provided with the status determination if the user is authorized to access the system.

139. (New) A method as in claim 137 wherein a request includes a unique identity for the animal and wherein the system stores information relating to the animal based on its identity.

140. (New) A method as in claim 137 further comprising determining the status of the animal based at least in part on previously stored information about the animal.

141. (New) A method as in claim 133 further comprising providing the user with a list of additional information that might be useful in making a status determination.

142. (New) A method comprising:

a) providing a system including a database of (a) a plurality statistical models that correlate biological factors of horses to known conditions in horses, and (b) statistical models that correlate known conditions in horses or biological factors of horses to known statuses of horses;

b) responsive to a user request for a status determination for a particular horse, said request including measures of a plurality of factors of the particular horse, the factors being obtained from cells in a biological sample, the sample being obtained from the particular horse in a single test, the factors being representative of the level, abundance or functional activity of a gene expression product in the cells, applying each statistical model from the database to at least

RECEIVED**CENTRAL FAX CENTER**

New Docket No.: 23558-028

Application No. 10/712,266

MAY 14 2008

Page 18 of 19

some of the biological factors in the request in order to determine whether the horse has a known condition or a known status; and

c) providing the user with the status determination of the horse.

143. (New) A method as in claim 142 wherein the user is at a remote location from the database and wherein the user is only provided with the status determination if the user is authorized to access the system.

144. (New) A method as in claim 142 wherein a request includes a unique identity for the horse and wherein the system stores information relating to the horse based on its identity.

145. (New) A method as in claim 142 further comprising determining the status of the horse based at least in part on previously stored information about the horse.

146. (New) A method as in claim 142 further comprising providing the user with a list of additional information about the horse that was not provided with the request and that might be useful in making a status determination about the horse.